

REMARKS/ARGUMENTS

Reconsideration of this application is requested. Claims 24-30, 36, 37, 40 and 43 are in the case.

I THE 35 USC 112, FIRST PARAGRAPH, REJECTION

Claims 24-30, 36, 37, 40 and 43 stand rejected under 35 USC 112, first paragraph, as allegedly failing to comply with the written description requirement. The Examiner asserts that the claims contain subject matter which was not described in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, has possession of the claimed invention. The Examiner has further asserted that:

"In this instance applicants are claiming a fusion molecule/product wherein neither the recognition site [E2 and/or E3 elements] or [sic] the binding element [ubiquitination element] have been sufficiently described in terms of their structure and function." (Emphasis in the original)

This rejection is respectfully traversed.

The invention as claimed is directed to a method of reducing the level and/or activity of a target protein in an eukaryotic cell via the activation of ubiquitination of the target protein. The method comprises contacting the cell with a compound comprising (a) a ubiquitination recognition element which is able to bind to either the E3 or E2 elements of the ubiquitination system, wherein the ubiquitination recognition element has a molecular weight less than 30,000 and has a binding affinity for said E3 and/or E2 elements of a ubiquitination system of at least 10^3 M^{-1} and (b) a target protein binding element that is able to bind specifically to the target protein. The target protein binding

element has a molecular weight of less than 30,000 and has a binding affinity for the target protein greater than 10^5 M^{-1} . The ubiquitination recognition element is covalently linked to the target protein binding element.

The above methodology is fully described in the originally filed specification, beginning with the last complete paragraph on page 11 and extending through to page 13. Target protein binding peptide elements are described in detail beginning at page 22, and ubiquitination recognition elements are described beginning at page 29 of the specification. Specific examples of ubiquitination recognition elements are provided at pages 31-37. The allegation that the ubiquitination recognition element "is indeterminate relative to the target to which it binds which is itself indeterminate" is thus unfounded. Additional description with respect to the claimed features is provided in the definitions section at pages 14 and 15 of the specification.

The Examiner has cited to the decided case in *Regents of the University of California v. Eli Lilly & Co.*, 119 F.3rd 1559 (CAFC 1997) for the proposition that "an applicant's specification must reasonably convey to those skilled in the art that the applicant was in possession of the claimed invention as of the date of invention" (per Examiner's quote at page 3 of the action). As will be clear from the above discussion referring to portions of the specification, the inventors clearly had possession of the claimed invention as of the filing date of the application.

The court further expanded on this in the later case of *Moba BV v. Diamond Automation, Inc.*, 325 F.3rd 1306 (CAFC 2003), wherein it stated:

The test for compliance with § 112 has always required sufficient information in the original disclosure to show that the inventor possessed the invention at the

time of the original filing. See *Vas-Cath*, 935 F.2d at 1561 (“Adequate description of the invention guards against the inventor’s overreaching by insisting that he recount his invention in such detail that his future claims can be determined to be encompassed within his original creation”). The possession test requires assessment from the viewpoint of one of skill in the art. *Id.* at 1563-64 (“the applicant must . . . convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention”) (emphasis in original); *Union Oil Co. of Cal. v. Atlantic Richfield Co.*, 208 F.3d 989, 997, 54 USPQ2d 1227, 1232 (Fed. Cir. 2000) (“The written description requirement does not require the applicant ‘to describe exactly the subject matter claimed, [instead] the description must clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed’”) (citation omitted). In *Enzo and Amgen*, the record showed that the specification that taught one of skill in the art to make and use an invention also convinced that artisan that the inventor possessed the invention. **Similarly in this case, the Lilly disclosure rule does not require a particular form of disclosure because one of skill could determine from the specification that the inventor possessed the invention at the time of filing.** (Emphasis added)

In addition, the claims are supported by an enabling disclosure (as evidenced by the withdrawal of the lack of enablement rejection), and the skilled artisan, based on the disclosure as discussed above, and the level of ordinary skill in the art, would readily conclude that the inventors had possession of the invention when the application was filed.

One of ordinary skill would understand the binding to the ubiquitination recognition element from basic education in biochemistry and biophysics, and would know how to obtain these binding species. In addition, the E2 and E3 elements are well known to persons of ordinary skill. The genome has been sequenced, and most of the E2 and E3 elements are available, either directly or via standard cloning methods known to persons of ordinary skill in the art. Moreover, all of the ubiquitination recognition elements can be joined to all target protein binding elements. While two such elements may be selected in ways that may involve challenging chemistry, it would

not be impossible. One skilled in the art on reading the specification would understand that the specific methods used in the selection of these elements is important, and that the inventors were in possession of that subject matter when the case was filed.

Based on the above, withdrawal of the 35 USC 112, first paragraph, rejection is believed to be in order. Such action is requested.

II. CLAIM INFORMALITY

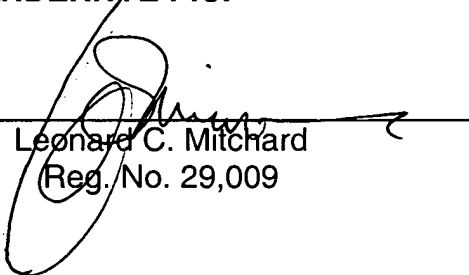
Claims 24 and 36 have been objected to as not providing proper antecedent basis for "the ubiquitination system". Claims 24 and 36 have been amended to deal with this objection. Withdrawal of the objection is respectfully requested.

Allowance of the application is awaited.

Respectfully submitted,

NIXON & VANDERHYTE P.C.

By: _____


Leonard C. Mitchard
(Reg. No. 29,009)

LCM:lfm
1100 North Glebe Road, 8th Floor
Arlington, VA 22201-4714
Telephone: (703) 816-4000
Facsimile: (703) 816-4100